IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

STATE OF NEBRASKA, by and through JON BRUNING, ATTORNEY GENERAL OF THE STATE OF NEBRASKA, et al., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Civil Action No. 4:12-cv-03035-CRZ

DEFENDANTS' MEMORANDUM OF LAW
IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

The Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010),[1] and implementing regulations, require all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain recommended preventive services without cost-sharing (such as a copayment, coinsurance, or a deductible).[2] As relevant here, except as to group health plans of certain religious employers (and group health insurance coverage sold in connection with those plans), the preventive services that must be covered include all Food and Drug Administration ("FDA")-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider. Plaintiffs – seven States, three non-profit organizations, and two individuals – brought suit on February 23, 2012, seeking to have the Court declare the preventive services coverage regulations invalid and enjoin their implementation. Plaintiffs claim the regulations violate their rights to free speech, free exercise of religion, and freedom of association protected by the First Amendment to the United States Constitution as well as the Religious Freedom Restoration Act ("RFRA").

Over the past few months, defendants have issued guidance on a temporary enforcement safe harbor and initiated a rulemaking to further amend the preventive services coverage regulations to address religious concerns such as those raised by plaintiffs in this case. The enforcement safe harbor provides that defendants will not bring any enforcement action against non-profit organizations with religious objections to providing contraceptive coverage (and

[1] Amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

[2] A grandfathered plan is one that was in existence on March 23, 2010 and that has not undergone any of a defined set of changes. 26 C.F.R. § 54.9815-1251T; 29 C.F.R. § 2590.715-1251; 45 C.F.R. § 147.140.

associated plans and issuers) if they meet certain criteria. The safe harbor protects such organizations until the first health plan year that begins on or after August 1, 2013. Moreover, defendants published an advance notice of proposed rulemaking ("ANPRM") in the Federal Register that confirms defendants' intent, before the expiration of the safe harbor period, to propose and finalize amendments to the preventive services coverage regulations to further accommodate non-exempt, non-grandfathered religious organizations' religious objections to covering contraceptive services. The ANPRM suggests ideas and solicits public comment on potential accommodations, including, but not limited to, requiring health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations that object to such coverage and simultaneously to offer contraceptive coverage directly to such organizations' plan participants, at no charge.

In light of these actions, this Court lacks jurisdiction to adjudicate plaintiffs' claims. As an initial matter, the organization plaintiffs have not alleged any imminent injury from the operation of the regulations. The organization plaintiffs sponsor group health plans for their employees, but they have not made factual allegations that establish that those plans – which according to the complaint do not cover contraceptive services – are ineligible for grandfather status. Thus, the organization plaintiffs have not shown that they are under any current obligation to offer coverage for contraceptive services. Moreover, even assuming the organization plaintiffs' group health plans are not grandfathered, the organization plaintiffs appear to qualify for the temporary enforcement safe harbor, and, indeed, they do not allege otherwise. Pursuant to the safe harbor, defendants will not take any enforcement action against the organization plaintiffs until at least August 1, 2013, by which time defendants will have

finalized amendments to the challenged regulations to accommodate the religious objections of organizations like the organization plaintiffs.

The individual plaintiffs – who are employed by religious organizations and obtain their health coverage through those organizations – lack standing for similar reasons. The individual plaintiffs currently have health coverage that does not cover contraception, and the allegations in the complaint do not establish that they will be unable to maintain that coverage for the foreseeable future either because their plans are not grandfathered or because their employers will not qualify for the temporary enforcement safe harbor. Further, when the safe harbor expires, the individual plaintiffs may well be able to continue receiving – through their religious organization employers – health coverage that does not cover contraceptive services in light of the rulemaking that defendants have initiated. The individual plaintiffs' speculation to the contrary – which relies on possible future events and potential future decisions made by parties that are not before this Court (e.g., the individual plaintiff's employers) – cannot establish standing.

The State plaintiffs also lack standing – both now and after the challenged regulations are finalized. It is well-established that a state cannot bring a *parens patriae* action on behalf of its citizens against federal defendants. *See, e.g.*, *Massachusetts v. Mellon*, 262 U.S. 447, 485-86 (1923). It is, after all, "the United States, and not the state, which represents [its citizens] as *parens patriae*." *Id*. at 486. In addition, the State plaintiffs have not established standing to bring this action on their own behalf. The alleged threat to the States' budgetary stability as a result of increased enrollment in the States' Medicaid programs is too speculative, remote, and indirect to support standing. It rests on hypotheticals about what independent actors may do in the future. The Eighth Circuit has rejected similar allegations of injury to a state, *see Iowa ex*

rel. Miller v. Block, 771 F.2d 347, 353-54 (8th Cir. 1985), and this Court should do the same here. Nor are the States the intended beneficiaries of the provisions on which their claims are based, as required by prudential principles of standing and Federal Rule of Civil Procedure 12(b)(6). The First Amendment and RFRA protect persons, not states. Indeed, states are not allowed to establish, much less exercise, religious beliefs.

Lastly, the Court lacks jurisdiction because plaintiffs' claims are not ripe. Plaintiffs' challenge to the preventive services coverage regulations is not fit for judicial review because defendants have initiated a rulemaking to amend the challenged regulations to further accommodate religious objections to providing contraceptive coverage. In the meantime, the temporary enforcement safe harbor will be in effect and plaintiffs will not suffer any hardship from the regulations they seek to challenge.

BACKGROUND

Prior to the enactment of the ACA, many Americans did not receive the preventive health care they needed to stay healthy, avoid or delay the onset of disease, lead productive lives, and reduce health care costs. Due in large part to cost, Americans used preventive services at about half the recommended rate. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) ("IOM REP."). Section 1001 of the ACA – which includes the preventive services coverage provision that is relevant here – seeks to cure this problem by making recommended preventive care affordable and accessible for many more Americans.

The preventive services coverage provision requires all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide

coverage for certain preventive services without cost-sharing.[3] 42 U.S.C. § 300gg-13. The preventive services that must be covered are: (1) evidence-based items or services that have in effect a rating of "A" or "B" from the United States Preventive Services Task Force ("USPSTF"); (2) immunizations recommended by the Advisory Committee on Immunization Practices; (3) for infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration ("HRSA")[4]; and (4) for women, such additional preventive care and screenings not described by the USPSTF as provided in comprehensive guidelines supported by HRSA. *Id.*

The requirement to provide coverage for recommended preventive services for women, without cost-sharing, was added as an amendment to the ACA during the legislative process. The Women's Health Amendment was intended to fill significant gaps relating to women's health that existed in the other preventive care guidelines identified in section 1001 of the ACA. *See* 155 Cong. Rec. S12019, S12025 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer) ("The underlying bill introduced by Senator Reid already requires that preventive services recommended by [USPSTF] be covered at little to no cost . . . . But [those recommendations] do not include certain recommendations that many women's health advocates and medical professionals believe are critically important . . . ."); 155 Cong. Rec. S12261, S12271 (daily ed. Dec. 3, 2009) (statement of Sen. Franken) ("The current bill relies solely on [USPSTF] to

[3] A group health plan includes a plan established or maintained by an employer that provides medical care to employees. 42 U.S.C. § 300gg-91(a)(1). Group health plans may be insured (i.e., medical care underwritten through an insurance contract) or self-insured (i.e., medical care funded directly by the employer). The ACA does not require employers to provide health coverage for their employees, but, beginning in 2014, certain large employers may face assessable payments if they fail to do so under certain circumstances. 26 U.S.C. § 4980H.

[4] HRSA is an agency within the Department of Health and Human Services.

determine which services will be covered at no cost. The problem is, several crucial women's health services are omitted. [The Women's Health Amendment] closes this gap.").

Research shows that cost-sharing requirements can pose barriers to preventive care and result in reduced use of preventive services, particularly for women. IOM REP. at 109; 155 Cong. Rec. at S12026-27 (daily ed. Dec. 1, 2009) (statement of Sen. Mikulski) ("We want to either eliminate or shrink those deductibles and eliminate that high barrier, that overwhelming hurdle that prevents women from having access to [preventive care]."). Indeed, a 2010 survey showed that less than half of women are up to date with recommended preventive care screenings and services. IOM REP. at 19. By requiring coverage for recommended preventive services and eliminating cost-sharing requirements, Congress sought to increase access to and utilization of recommended preventive services. 75 Fed. Reg. 41726, 41728 (July 19, 2010). Increased use of preventive services will benefit the health of individual Americans and society at large: individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease; healthier workers will be more productive with fewer sick days; and increased utilization will result in savings due to lower health care costs. 75 Fed. Reg. at 41728, 41733; IOM REP. at 20.

Defendants issued interim final regulations implementing the preventive services coverage provision on July 19, 2010. 75 Fed. Reg. 41726. The interim final regulations provide, among other things, that a group health plan or health insurance issuer offering non-grandfathered health coverage must provide coverage for newly recommended preventive services, without cost-sharing, for plan years (or, in the individual market, policy years) that begin on or after the date that is one year after the date on which the new recommendation is

issued. 26 C.F.R. § 54.9815-2713T(b)(1); 29 C.F.R. § 2590.715-2713(b)(1); 45 C.F.R. § 147.130(b)(1).

Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services ("HHS") tasked the Institute of Medicine ("IOM")[5] with "reviewing what preventive services are necessary for women's health and well-being" and developing recommendations for comprehensive guidelines. IOM REP. at 2. IOM conducted an extensive science-based review and, on July 19, 2011, published a report of its analysis and recommendations. *Id*. at 20-26. The report recommended that HRSA guidelines include, among other things, well-woman visits, breastfeeding support, domestic violence screening, and, as relevant here, "the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." *Id*. at 10-12. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices. FDA, Birth Control Guide, *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118465.htm (last visited Apr. 5, 2012).

On August 1, 2011, HRSA adopted IOM's recommendations in full, subject to an exemption relating to certain religious employers authorized by an amendment to the interim final regulations. *See* HRSA Guidelines, *available at* http://www.hrsa.gov/womensguidelines/ (last visited Apr. 5, 2012). The amendment to the interim final regulations, issued on the same day, authorized HRSA to exempt group health plans sponsored by certain religious employers

[5] IOM was established in 1970 by the National Academy of Sciences and is funded by Congress. IOM REP. at iv. It secures the services of eminent members of appropriate professions to examine policy matters pertaining to the health of the public and provides expert advice to the federal government. *Id*.

(and associated group health insurance coverage) from any requirement to cover contraceptive services under HRSA's guidelines. 76 Fed. Reg. 46621 (Aug. 3, 2011); 45 C.F.R. § 147.130(a)(1)(iv)(A). To qualify for the exemption, an employer must meet all of the following criteria:

> (1) The inculcation of religious values is the purpose of the organization.
>
> (2) The organization primarily employs persons who share the religious tenets of the organization.
>
> (3) The organization serves primarily persons who share the religious tenets of the organization.
>
> (4) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

45 C.F.R. § 147.130(a)(1)(iv)(B). The sections of the Internal Revenue Code referenced in the fourth criterion refer to "churches, their integrated auxiliaries, and conventions or associations of churches," as well as "the exclusively religious activities of any religious order," that are exempt from taxation under 26 U.S.C. § 501(a). 26 U.S.C. § 6033(a)(1), (a)(3)(A)(i), (a)(3)(A)(iii). Thus, as relevant here, the amended interim final regulations required non-grandfathered plans that do not qualify for the religious employer exemption to provide coverage for recommended contraceptive services, without cost-sharing, for plan years (or, in the individual market, policy years) beginning on or after August 1, 2012.

Defendants requested comments on the amended interim final regulations and specifically on the definition of religious employer contained in those regulations. 76 Fed. Reg. at 46623. After carefully considering the more than 200,000 comments they received, defendants decided to adopt in final regulations the definition of religious employer contained in the amended interim final regulations while also creating a temporary enforcement safe harbor for plans sponsored by certain non-profit organizations with religious objections to contraceptive

coverage that do not qualify for the religious employer exemption. 77 Fed. Reg. 8725, 8727 (Feb. 15, 2012).

Pursuant to the temporary enforcement safe harbor, defendants will not take any enforcement action against an employer, group health plan, or group health insurance issuer with respect to a non-exempt, non-grandfathered group health plan that fails to cover some or all recommended contraceptive services and that is sponsored by an organization that meets all of the following criteria:

(1) The organization is organized and operates as a non-profit entity.

(2) From February 10, 2012 onward, contraceptive coverage has not been provided at any point by the group health plan sponsored by the organization, consistent with any applicable state law, because of the religious beliefs of the organization.

(3) The group health plan sponsored by the organization (or another entity on behalf of the plan, such as a health insurance issuer or third-party administrator) provides to plan participants a prescribed notice indicating that the plan will not provide contraceptive coverage for the first plan year beginning on or after August 1, 2012.

(4) The organization self-certifies that it satisfies the three criteria above, and documents its self-certification in accordance with prescribed procedures.[6]

The enforcement safe harbor will be in effect until the first plan year that begins on or after August 1, 2013. Guidance at 3. By that time, defendants expect that significant changes to the preventive services coverage regulations will have altered the landscape with respect to religious accommodations under the regulations by providing further relief to certain religious organizations.

Those intended changes, which were first announced when defendants finalized the religious employer exemption, will establish alternative means of providing contraceptive

[6] HHS, Guidance on the Temporary Enforcement Safe Harbor ("Guidance"), at 3 (Feb. 10, 2012), *available at* http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf (last visited Apr. 5, 2012); 75 Fed. Reg. 16501, 16504 (Mar. 21, 2012).

coverage without cost-sharing while also accommodating non-exempt, non-grandfathered religious organizations' religious objections to covering contraceptive services. 77 Fed. Reg. at 8728. Defendants began the process of amending the regulations on March 21, 2012, when they published an ANPRM in the Federal Register. 77 Fed. Reg. 16501 (Mar. 21, 2012). The ANPRM "presents questions and ideas" on potential means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations' liberty interests. *Id*. at 16503. The purpose of the ANPRM is to provide "an early opportunity for any interested stakeholder to provide advice and input into the policy development relating to the accommodation to be made" in the forthcoming amendments to the regulations. *Id*. Among other options, the ANPRM suggests requiring health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations that object to such coverage on religious grounds and simultaneously to offer contraceptive coverage directly to the organization's plan participants, at no charge. *Id*. at 16505. The ANPRM also suggests ideas and solicits comments on potential ways to accommodate religious organizations that sponsor self-insured group health plans for their employees. *Id*. at 16506-07.

After receiving comments on the ANPRM, defendants will publish a notice of proposed rulemaking, which will be subject to further public comment before defendants issue further amendments to the preventive services coverage regulations. *Id*. at 16501. Defendants intend to finalize the amendments to the regulations such that they are effective by the end of the temporary enforcement safe harbor. *Id*. at 16503.

STANDARD OF REVIEW

Defendants move to dismiss this case in its entirety for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. The party invoking federal

jurisdiction bears the burden of establishing its existence. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 104 (1998); *Wilkinson v. United States*, 440 F.3d 970, 977 (8th Cir. 2006). Where, as here, defendants challenge jurisdiction on the face of the complaint, the complaint must plead sufficient facts to establish that jurisdiction exists. This Court must determine whether it has subject matter jurisdiction before addressing the merits of the complaint. *See Steel Co.*, 523 U.S. at 94-95.

Defendants also move to dismiss the State plaintiffs' claims under Rule 12(b)(6) for failure to state a claim upon which relief may be granted. Under this Rule, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009).

ARGUMENT

I. THE COURT SHOULD DISMISS THIS CASE FOR LACK OF JURISDICTION BECAUSE PLAINTIFFS LACK STANDING

"[S]tanding is an essential and unchanging part of the case-or-controversy requirement of Article III [of the Constitution]," and it is fundamental to the court's jurisdiction to hear a case. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). The "irreducible constitutional minimum of standing" requires a plaintiff to demonstrate (1) it has suffered an injury in fact; (2) the existence of a causal connection between the alleged injury and conduct that is fairly traceable to the defendant; and (3) it is likely the requested relief will redress the alleged injury. *Id*. at 560–61.

An injury in fact is "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Id*. at 560 (quotations omitted). The harm must be "direct and palpable." *Carson v. Pierce*, 719 F.2d 931,

934 (8th Cir. 1983). Allegations of possible future injury do not suffice; rather, "[a] threatened injury must be certainly impending to constitute injury in fact." *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990) (quotation omitted). A plaintiff that "alleges only an injury at some indefinite future time" has not shown an injury in fact, particularly where "the acts necessary to make the injury happen are at least partly within the plaintiff's own control." *Lujan*, 504 U.S. at 564 n.2. In these situations, "the injury [must] proceed with a high degree of immediacy, so as to reduce the possibility of deciding a case in which no injury would have occurred at all." *Id.*

A. The Organization Plaintiffs Lack Standing

There are three organization plaintiffs. Catholic Social Services describes itself as a non-profit corporation affiliated with the Catholic Diocese of Lincoln, Nebraska, that provides "faith-based charity services" to persons in southern Nebraska. Compl. ¶¶ 34-35. It states that it has "more than 50 persons on staff." *Id.* ¶ 36. Pius X Catholic High School describes itself as a non-profit corporation with more than 70 faculty and staff and the "sole Catholic high school" for the City of Lincoln, Nebraska. *Id.* ¶¶ 44-45. The Catholic Mutual Relief Society of America states that it is "a non-profit religious 501(c)(3) organization with its principle place of business located in Omaha, Nebraska." *Id.* ¶ 51. The organization plaintiffs allege that they currently make available to their employees group health plans that do not cover contraception. *Id.* ¶¶ 39, 41, 47, 49, 52, 56. They further allege that "[h]ealth insurance coverage of services for purposes of contraception, abortifacients, or sterilization is in contravention with Catholic teaching and doctrine adhered to and followed by [the organization plaintiffs]." *Id.* ¶ 40; *accord id.* ¶¶ 48, 57. Catholic Social Services and The Catholic Mutual Relief Society of America assert that they do not qualify for the religious employer exemption because the inculcation of religious values is

not their primary purpose and they employ or serve persons who do not share their religious tenets. *Id*. ¶¶ 37-38, 53, 55.

These allegations do not establish standing because they fail to demonstrate a concrete and imminent injury resulting from the operation of the preventive services coverage regulations. First, the organization plaintiffs have not made sufficient factual allegations to show that the group health plans they offer to their employees are not eligible for grandfather status. The preventive services coverage regulations do not apply to grandfathered plans. 42 U.S.C. § 18011(a)(2); 26 C.F.R. § 54.9815-1251T; 29 C.F.R. § 2590.715-1251; 45 C.F.R. § 147.140. A grandfathered plan is a health plan in which at least one individual was enrolled on March 23, 2010 and that has continuously covered at least one individual since that date. 42 U.S.C. § 18011(a)(2); 26 C.F.R. § 54.9815-1251T(a), (g)(1); 29 C.F.R. § 2590.715-1251(a), (g)(1); 45 C.F.R. § 147.140(a), (g)(1). A grandfathered plan may lose its grandfather status if, compared to its existence on March 23, 2010, it eliminates all or substantially all benefits to diagnose or treat a particular condition, increases a percentage cost-sharing requirement, significantly increases a fixed-amount cost-sharing requirement, significantly reduces the employer's contribution, or imposes or tightens an annual limit on the dollar value of any benefits. 26 C.F.R. § 54.9815-1251T(a), (g)(1); 29 C.F.R. § 2590.715-1251(a), (g)(1); 45 C.F.R. § 147.140(a), (g)(1).

The Catholic Mutual Relief Society of America concedes that its group health plan is grandfathered. Compl. ¶ 59. Catholic Social Services and Pius X Catholic High School assert that their group health plans are not grandfathered, *id*. ¶¶ 43, 50, but they do not allege any facts to support this legal conclusion. *See Iqbal*, 129 S. Ct. at 1949 (observing that "naked assertion[s] devoid of further factual enhancement" are insufficient to survive a motion to dismiss (quotations omitted)); *Walker v. Barrett*, 650 F.3d 1198, 1209 (8th Cir. 2011) ("[L]egal

conclusions, without any supporting factual allegations, are insufficient to survive a motion to dismiss."); *United States v. Metro. St. Louis Sewer Dist.*, 569 F.3d 829, 834 (8th Cir. 2009) ("[A] plaintiff must clearly allege facts showing an injury in fact[.]"). Catholic Social Services and Pius X Catholic High School do not allege that their group health plans were not in place on March 23, 2010, or that their plans have not continuously covered at least one individual since that date, or that they have altered their plans in a way that would cause them to lose grandfather status. Nor do they allege that they will alter their health plans in such a way in the imminent future. Plaintiffs do contend that the loss of grandfather status "in the foreseeable future" is "inevitabl[e]." Compl. ¶ 89. But none of the organization plaintiffs alleges specific plans to alter their health plan in a substantial way. "[A]ssumed future intent," *County of Mille Lacs v. Benjamin*, 361 F.3d 460, 464 (8th Cir. 2004), and "'some day' intentions – without any description of concrete plans," *Lujan*, 504 U.S. at 564 – do not establish an injury in fact. *See also id*. at 564 n.2 (allegations of injury "at some indefinite future time" do not establish an injury in fact, particularly where "the acts necessary to make the injury happen are at least partly within the plaintiff's own control"). Accordingly, the allegations in the complaint simply do not show that the organization plaintiffs will be required by the preventive services coverage regulations to provide coverage for contraceptive services – as opposed to continuing to offer a grandfathered plan that does not, and presumably would not, cover contraceptive services.[7]

Second, even if the organization plaintiffs had sufficiently alleged that their group health plans are not grandfathered, they still would not have alleged an injury in fact. Under the enforcement safe harbor, defendants will not take any enforcement action against an organization

[7] Unlike the other two organization plaintiffs, Pius X Catholic High School does not allege that it is ineligible for the religious employer exemption. For this additional reason, Pius X Catholic High School has not alleged an injury resulting from the challenged regulations.

that qualifies for the safe harbor until the first plan year that begins on or after August 1, 2013. Guidance at 3. The organization plaintiffs make no effort to show that they will not be protected by the enforcement safe harbor. Indeed, the organization plaintiffs' own description of themselves – as non-profit organizations that do not provide contraception coverage in their group health plans (Compl. ¶¶ 34, 41, 44, 49, 51, 56) – strongly suggests that they do qualify for the enforcement safe harbor. *See* Guidance at 3. Thus, the earliest the organization plaintiffs could be subject to any enforcement action by defendants for failing to provide contraceptive coverage is August 1, 2013. With such a long time before the inception of any possible injury and the challenged regulations undergoing amendment before then, the organization plaintiffs cannot satisfy the imminence requirement for standing; the asserted injury is simply "too remote temporally." *See McConnell v. FEC*, 540 U.S. 93, 226 (2003) (concluding Senator lacked standing based on claimed desire to air advertisements five years in the future), *overruled in part on other grounds*, *Citizens United v. FEC*, 130 S. Ct. 876 (2010); *Whitmore*, 495 U.S. at 159-60.

This defect in the organization plaintiffs' suit does not implicate a mere technical issue of counting intermediate days. Nor does it rest on the truism that a final regulation is always subject to change by the agency that promulgated it; the ANPRM goes much further than that by promising imminent regulatory amendments. Thus, the defect in plaintiff's case goes to the fundamental limitations on the role of federal courts. The "underlying purpose of the imminence requirement is to ensure that the court in which suit is brought does not render an advisory opinion in 'a case in which no injury would have occurred at all.'" *Animal Legal Def. Fund, Inc. v. Espy*, 23 F.3d 496, 500 (D.C. Cir. 1994) (*quoting Lujan*, 504 U.S. at 564 n.2). The ANPRM published in the Federal Register confirms, and seeks comment on, defendants' intention to propose further amendments to the preventive services coverage regulations that will

accommodate the concerns of religious organizations that object to providing contraceptive coverage for religious reasons, like the organization plaintiffs. 77 Fed. Reg. at 16501. The ANPRM provides plaintiffs, and any other interested party, with the opportunity to, among other things, comment on ideas suggested by defendants for accommodating religious organizations, offer new ideas to "enable religious organizations to avoid . . . objectionable cooperation when it comes to the funding of contraceptive coverage," and identify considerations defendants should take into account when amending the regulations. *Id*. at 16503, 16507. Defendants, moreover, have indicated that they intend to finalize the amendments to the regulations before the rolling expiration of the temporary enforcement safe harbor starting on August 1, 2013. *Id*. at 16503; *see also* 77 Fed. Reg. at 8728. In light of the forthcoming amendments, and the opportunity the rulemaking process provides for plaintiffs to help shape those amendments, there is no reason to suspect that the organization plaintiffs will be required to sponsor a health plan that covers contraceptive services in contravention of their religious beliefs once the enforcement safe harbor expires. At the very least, given the anticipated changes to the preventive services coverage regulations, the organization plaintiffs' claim of injury after the temporary enforcement safe harbor expires, if any, would differ substantially from their current claim of injury. And, given the existing enforcement safe harbor, there is no basis for this Court to consider the merits of plaintiffs' complaint at this juncture.[8]

[8] Plaintiffs maintain that nothing prevents defendants from "unilaterally *withdrawing*" the temporary enforcement safe harbor at any time and thus there is no guarantee that the organization plaintiffs will be protected from enforcement action by defendants until August 1, 2013. Compl. ¶ 73. Speculation that the defendants will take back the promised safe harbor – which was issued as formal guidance by the Secretary of Health and Human Services, *see* Guidance, and has been repeatedly referenced in the Federal Register, *see, e.g.*, 77 Fed. Reg. 8725, 8728 (Feb. 15, 2012); 77 Fed. Reg. at 16502-03 – is not only dubious, it is also insufficient to establish an injury. Indeed, the Eighth Circuit rejected an argument similar to the one plaintiffs make here in *Boyle v. Anderson*, 68 F.3d 1093, 1100 (8th Cir. 1995). In that case, the

Accordingly, the Court should dismiss the organization plaintiffs' claims for lack of standing.

B. The Individual Plaintiffs Lack Standing

The two individual plaintiffs – who are employed by religious organizations and obtain their health coverage through those organizations – lack standing for reasons similar to those set forth above with respect to the organization plaintiffs.

Sister Mary Catherine describes herself as a "Catholic nun affiliated with the School Sisters of Christ the King." Compl. ¶ 16. She states that she is currently covered by a non-grandfathered health plan, which does not cover contraception, through the Catholic Diocese of Lincoln, Nebraska. *Id.* ¶¶ 17, 19, 21. Stacy Molai describes herself as a "missionary employed by the Fellowship of Catholic University Students ("FOCUS"), a Catholic organization engaged in ministry and outreach on college campuses." *Id.* ¶ 23. She states that she is currently covered by a grandfathered health plan, which does not cover contraception, through her employer, FOCUS. *Id.* ¶¶ 24, 26, 31. Both Sister Mary Catherine and Stacy Molai allege that health insurance coverage for contraception is in contravention of their religious beliefs, *id.* ¶¶ 18, 25, and that they will drop such coverage if retaining it would result in the "subsidization" of contraception, *id.* ¶¶ 20, 30. Neither of the individual plaintiffs, however, allege that they pay any portion of the premium for their health coverage or that they will be required to do so in the future. Stacy Molai further alleges that she suffers from an incurable chronic illness that requires substantial ongoing medical care. *Id.* ¶¶ 27-29.

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plaintiff sought to challenge state law reporting requirements that did not apply to it based on the supposition that the state "might at some point in the future change its position and require compliance with the data requirements." *Id.* The court, however, refused to issue "an advisory opinion to deal with the possibility that at some point in the future the State" might "reverse [its] position." *Id.* "[C]onjectur[e] about "possible future injury," the court explained, "does not meet the requirements for an injury in fact." *Id.*

The individual plaintiffs' claims are premised on a possible future world in which the individual plaintiffs will not be able to obtain health coverage without contraception coverage. But the individual plaintiffs currently have health coverage that does not cover contraception, and the allegations in the complaint do not show that they will be unable to maintain such coverage for the foreseeable future or that they will somehow be required to "subsidize" contraception coverage. Further, any potential injury to the individual plaintiffs would be attributable to the currently unknown actions of the individual plaintiff's employers. And those employers are not before the Court. Thus, the individual plaintiffs have not alleged an imminent and concrete injury that is fairly traceable to the preventive services coverage regulations.

First, the individual plaintiffs have not sufficiently alleged that their current health plans, which do not cover contraception, are not grandfathered and thus excluded from the requirement to cover contraceptive services. Indeed, Stacey Molai admits that her health plan is grandfathered. Compl. ¶ 31. She speculates that her employer could change the health plan in the future in a way that would cause it to lose grandfather status, *id*. ¶ 32, but such generalized conjecture about possible future events – particularly events that hinge on the independent actions of parties not before this Court – cannot establish standing. *See Lujan*, 504 U.S. at 561, 564; *Whitmore*, 495 U.S. at 158; *County of Mille Lacs*, 361 F.3d at 464. Sister Mary Catherine alleges that her health insurance plan is not grandfathered, Compl. ¶ 21, but she does not provide any of the necessary factual allegations to support this legal conclusion.[9] *See Iqbal*, 129 S. Ct. at 1949; *Walker*, 650 F.3d at 1209; *Metro. St. Louis Sewer Dist.*, 569 F.3d at 834. The individual plaintiffs, therefore, simply have not shown that the health plans under which they are currently

[9] In addition, neither Sister Mary Catherine nor Stacy Molai has alleged that her employer is ineligible for the religious employer exemption. *See* 45 C.F.R. § 147.130(a)(1)(iv).

covered will be required to cover contraception as a result of the preventive services coverage regulations.

Second, even if the individual plaintiffs' health plans were not grandfathered, the individual plaintiffs still would not have made sufficient allegations to establish standing. The individual plaintiffs make no effort to show that their employers will not be protected by the temporary enforcement safe harbor, such that their employers can continue to offer a health plan that does not cover contraception without fear of an enforcement action by defendants until at least August 1, 2013. Indeed, the individual plaintiffs' description of their employers, *see* Compl. ¶¶ 16, 17, 19, 23, 26, strongly suggests that the employers do qualify for the enforcement safe harbor. *See* Guidance at 3. There is, therefore, no reason to suspect that the individual plaintiffs will be unable to maintain – through their religious organization employers – health coverage that does not cover contraceptive services until at least August 1, 2013.[10]

Moreover, by that time, defendants will have finalized amendments to the preventive services coverage regulations that will accommodate additional religious organizations' religious objections to providing contraception coverage. Those amendments are likely to affect the individual plaintiffs as well, by providing them with a mechanism – through their religious organization employers – to obtain health coverage that does not cover contraception. *See* 77 Fed. Reg. at 16505 (suggesting, among other options, that amendments might require health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations that object to such coverage on religious grounds). And any suggestion that the individual plaintiffs will be unable to obtain such coverage through their employer after the

[10] Any decision by the individual plaintiffs' employers to forego the benefit of the temporary enforcement safe harbor is not only speculative at this point but also would not establish an injury fairly traceable to the challenged regulations. *See Lujan*, 504 U.S. at 561.

enforcement safe harbor expires is entirely speculative at this point. At the very least, given the anticipated amendments, the individual plaintiffs' claim of injury after the temporary enforcement safe harbor expires, if any, would differ substantially from their current claim of injury. *See Metro. St. Louis Sewer Dist.*, 569 F.3d at 835-837; *Johnson v. Missouri*, 142 F.3d 1087, 1089-90 (8th Cir. 1998) (rejecting standing where "a number of things [had to] occur before [plaintiffs would] suffer an actual or even an imminent injury" and, at the time the suit was brought, "the timing and type of injury to the [plaintiffs could not] be determined"). Because the individual plaintiffs' allegations of injury rest on possible future events and decisions independent actors not before the Court may make in the future, the individual plaintiffs' claims should be dismissed for lack of standing.

C. The State Plaintiffs Lack Standing[11]

The States appear to pursue two theories of standing. First, they seek to bring a *parens patriae* action on behalf of their citizens to protect their citizens' rights under the First Amendment and RFRA. *See* Compl. ¶¶ 9-15, 77. Second, the States purport to sue on their own behalf, alleging their budgetary stability will be adversely affected if more citizens enroll in Medicaid as a result of religious organizations dropping health coverage for their employees or religious charities ceasing to serve persons who do not share their religious beliefs. *Id*. ¶¶ 85-87. Neither theory satisfies the States' burden to demonstrate standing.

[11] The Court should address the State plaintiffs' standing even if it determines that one or more of the organization or individual plaintiffs have standing. *See Iowa ex rel. Miller v. Block*, 771 F.2d 347, 354-55 (8th Cir. 1985) (dismissing State for lack of standing even though defendant did not challenge standing of individual plaintiff); *see also Allen v. Wright*, 468 U.S. 737, 752 (1984) (Article III standing limitations are designed "to ascertain whether the *particular plaintiff* is entitled to an adjudication of the *particular claims* asserted" (emphasis added)).

1. The States Cannot Bring a *Parens Patriae* Action

The doctrine of *parens patriae* permits a state to sue to vindicate the interests of its citizens in some instances. *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 601 (1982). The Supreme Court, however, made clear more than 80 years ago that a state cannot bring a *parens patriae* action against federal defendants. *See Massachusetts v. Mellon*, 262 U.S. at 485-86. In dismissing an action brought by Massachusetts to exempt its citizens from a federal statute designed to "protect the health of mothers and infants," the Court explained that the citizens of a state "are also citizens of the United States," and therefore "[i]t cannot be conceded that a state, as *parens patriae*, may institute judicial proceedings to protect citizens of the United States from the operation of the statutes thereof." *Id*. at 478, 485. The Court stressed that "it is no part of [a state's] duty or power to enforce [its citizens'] rights in respect of their relations with the federal government;" "it is the United States, and not the state, which represents [its citizens] as *parens patriae*." *Id*. at 485-86.

The Supreme Court has consistently applied this principle since *Mellon* to dismiss actions brought by a state as *parens patriae* against federal defendants. *See Florida v. Mellon*, 273 U.S. 12,18 (1927) (relying on *Mellon* to dismiss Florida's challenge to a federal inheritance tax based on alleged injury to its citizens); *South Carolina v. Katzenbach*, 383 U.S. 301, 324 (1966) (concluding South Carolina lacked standing as *parens patriae* to invoke the Due Process Clause or the Bill of Attainder Clause against the federal government); *see also Snapp*, 458 U.S. at 610 n.16 ("A State does not have standing as *parens patriae* to bring an action against the Federal Government."); *Massachusetts v. EPA*, 549 U.S. 497, 520 n.17 (2007) (observing that *Mellon* "prohibits" allowing a state "'to protect her citizens from the operation of federal statutes'"). And lower courts – including the Eighth Circuit – have done the same. *See Iowa ex rel. Miller*,

771 F.2d at 354-55 (concluding Iowa lacked standing as *parens patriae* to sue federal defendants; "[to] allow the State to proceed as *parens patriae*" against federal defendants "would intrude on the sovereignty of the federal government and ignore important considerations of our federalist system"); *see also Virginia. ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 271 (4th Cir. 2011); *Wyoming ex rel. Sullivan v. Lujan*, 969 F.2d 877, 883 (10th Cir. 1992); *Pennsylvania v. Kleppe*, 533 F.2d 668, 676-77 (D.C. Cir. 1976); *People ex. rel. Hartigan v. Cheney*, 726 F. Supp. 219, 222-23 (C.D. Ill. 1989).

Because a state cannot bring a *parens patriae* suit against federal defendants, the State plaintiffs cannot pursue this action under a *parens patriae* theory.

2. The States Cannot Sue On Their Own Behalf

a. The States Have Not Alleged an Imminent, Actual, and Concrete Injury to Their Own Interests

In some circumstances, a state may have standing to challenge federal action that threatens its own distinct interests. As with any other party, however, the harm to the state's interests must be "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not 'conjectural' or 'hypothetical.'" *Lujan*, 504 U.S. at 560-61. A state suffers a cognizable injury when, for example, its physical territory such as its "coastal land" is harmed. *See Massachusetts v. EPA*, 549 U.S. at 522-23. A state likewise may challenge a measure commanding the state itself to act, *see New York v. United States*, 505 U.S. 144 (1992) (standing to challenge federal law requiring State to take title to nuclear waste or enact federally-approved regulations), or that prohibits it from acting, *see Oregon v. Mitchell*, 400 U.S. 112 (1970) (standing to challenge federal law barring literacy-test or durational-residency requirements in elections and requiring State to enfranchise 18-year-olds).

The State plaintiffs' allegations of harm to their own interests in this case are a far cry from the actual or imminent injuries alleged in the cases cited above. The States allege that, if religious organizations were to stop providing health coverage to their employees, those employees would enroll in the States' Medicaid programs. Compl. ¶ 85. They also assert that religious organizations would stop providing charitable services to persons who do not share the organizations' religious beliefs in an effort to qualify for the religious employer exemption and, as a result, the individuals previously served by these organizations would turn to the States' Medicaid programs. *Id.* ¶ 87. The States claim this predicted increase in the number of individuals enrolled in their Medicaid programs would threaten the States' "budgetary stability." *Id*. ¶¶ 86-87.

These allegations amount to no more than "conjecture based on speculation that is bottomed on surmise," and, thus, they do not establish standing. *Wyoming ex rel. Sullivan*, 969 F.2d at 882. Indeed, the Eighth Circuit rejected similar allegations of injury to a state in *Iowa ex rel. Miller*. 771 F.2d 347. In that case, Iowa sued to compel the Secretary of Agriculture to implement various federal agricultural disaster relief programs following a drought in the State. *Id*. at 348. Like the State plaintiffs here, Iowa alleged that the Secretary's failure to implement the programs would adversely affect the State's financial resources by imposing "increased responsibility for the welfare and support of [] affected citizens" on the State while also causing a decrease in the State's tax revenues. *Id*. at 353. Iowa relied on speculative inferences – not unlike the leaps of logic the State plaintiffs make here – to contrive this speculative harm. Iowa asserted that, without the federal disaster relief programs, agriculture production in the State would decline and agriculturally-based industries would move out of State. *Id*. These occurrences, Iowa concluded, would "forc[e] unemployment up and state tax revenues down."

Id. The Eighth Circuit rejected these allegations of injury, concluding they were far too speculative, remote, and indirect to support standing. *Id*. at 354. *See also Florida*, 273 U.S. at 17-18 (rejecting standing notwithstanding Florida's allegation that challenged federal law would induce citizens to remove property from the State thereby diminishing the State's tax revenues); *People ex. rel. Hartigan*, 726 F. Supp. at 223 (concluding Illinois lacked standing despite claim that challenged federal law would require "increased spending by the state on such programs as unemployment compensation benefits and public assistance"). This Court should reach the same result here.

As an initial matter, in light of the forthcoming amendments to the regulations that are intended to further accommodate religious objections to providing contraception coverage, it would be speculative to suggest that religious organizations will stop providing health coverage to their employees because of the preventive services coverage regulations. Indeed, the State plaintiffs do not even go so far as to make such a claim. Their allegation instead is framed as a "what if." Compl. ¶ 85 ("*If* religious organization employers *were to* cease provision of health insurance . . . ." (emphasis added)). Such speculation about possible future events cannot constitute an injury in fact. *Whitmore*, 495 U.S. at 158; *Metro. St. Louis Sewer Dist.*, 569 F.3d at 835-837 (concluding association did not have standing to intervene in lawsuit because alleged injury – an increase in sewer rates – depended on a number of contingencies and thus constituted mere speculation); *Nolles v. State Comm. for Reorganization of Sch. Dists.*, 524 F.3d 892, 901 (8th Cir. 2008) (no standing where "claimed injury" was "the potential for increased property taxes without a hearing").

The State plaintiffs' allegation regarding the potential future decisions of religious charities to cease serving certain individuals is similarly theoretical. Conjecture about decisions

independent actors may make in the future is insufficient to support standing. *See County of Mille Lacs*, 361 F.3d at 464 (observing that "speculative harms based upon the assumed future intent" do not establish an injury in fact).[12]

Furthermore, even if the States' hypotheticals were to come to pass someday, it is simply wrong to suggest – as the States appear to do – that the employees and beneficiaries of these religious organizations would "invariably" enroll in Medicaid. Compl. ¶ 85. The eligibility requirements for individuals that a state's Medicaid program must cover – if the state elects to participate in Medicaid – are based on an individual's income and physical condition, not whether the individual has health insurance coverage. *See* 42 U.S.C. § 1396a(a)(10)(A)(i). Thus, an individual who is not otherwise eligible for Medicaid does not become eligible merely because she is no longer receiving health insurance through her employer.[13] Because the States' allegations of injury to their "budgetary stability," Compl. ¶86, appears to be based on the false premise that individuals not otherwise eligible for Medicaid will become eligible for, and in fact enroll in, Medicaid if religious organizations stop providing health coverage or charitable services (which is itself a highly speculative proposition), the States have not alleged a

[12] The State plaintiffs' alleged injury also is not fairly traceable to the preventive services coverage regulations. It is based on the States' predictions about the future decisions of employers, charitable organizations, and individuals – decisions that will no doubt be based on factors other than the existence of the preventive services coverage regulations. *See Lujan*, 504 U.S. at 562 (observing that standing is "substantially more difficult to establish" where the alleged injury "depends on the unfettered choices made by independent actors not before the court[] and whose exercise of broad and legitimate discretion the court[] cannot presume either to control or to predict" (quotation omitted)).

[13] Conversely, an individual who is eligible for Medicaid remains eligible even if she is provided health coverage through her employer. *See* 42 U.S.C. § 1396e(c)(2) ("The fact that an individual is enrolled in a group health plan under this section shall not change the individual's eligibility for benefits under the State plan, except insofar as section 1396a(a)(25) of this title provides that payment for such benefits shall first be made by such plan.").

cognizable injury.[14] In sum, the States' allegations of possible second-order ricochet effects on their budgetary stability fail to establish standing.

b. The States' Alleged Injury Does Not Fall Within the Zone of Interests to be Protected by the First Amendment or RFRA

In addition to the constitutional requirements for standing set forth in *Lujan*, courts also adhere to a set of prudential principles that bear on the question of standing. *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 474 (1982). These prudential principles were developed by the judiciary to "avoid deciding questions of broad social import where no individual rights would be vindicated and to limit access to the federal courts to those litigants best suited to assert a particular claim." *Gladstone Realtors v. Village of Bellwood*, 441 U.S. 91, 99-100 (1979). One such principle requires that the plaintiff's complaint fall within "the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Association of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970). "[W]here the plaintiff is not itself the subject of the contested regulatory action, the [zone-of-interest] test denies a right of review if the plaintiff's interests are so marginally related to or inconsistent with the purposes of the statute [or constitutional provision] that it cannot reasonably be assumed that Congress [or the Framers] intended to permit the suit." *Clarke v. Securities Indus. Ass'n*, 479 U.S. 388, 399-400 (1987).

[14] Even if the States did not have this apparent false premise problem, they still would lack standing. State participation in the Medicaid program is voluntary, but, once states choose to participate, they must offer benefits to certain individuals as a condition of participation. It is difficult to see how a State can claim injury on the ground that its citizens will choose to accept benefits the State has chosen to offer them under state law. *See Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (concluding States that enacted tax credits for individuals' taxes paid to other States did not have standing to sue other States for damages, because the "injuries to the plaintiffs' fiscs were self-inflicted, resulting from decisions by their respective state legislatures").

The necessary link between the State plaintiffs and the provisions on which their claims rely – the First Amendment and RFRA – is absent here. The First Amendment and RFRA are intended to protect individuals, not states. *See Rasul v. Myers*, 563 F.3d 527, 532-33 (D.C. Cir. 2009); *Parker v. District of Columbia*, 478 F.3d 370, 383 (D.C. Cir. 2007). The provisions, moreover, are designed to ensure religious liberty, not state solvency. The States' asserted interest in their budgetary stability simply does not fall within these zones of interest. *See South Dakota v. U.S. Dep't of Interior*, 665 F.3d 986, 990-91 (8th Cir. 2012) (concluding that South Dakota lacked prudential standing to challenge, under the Due Process Clause, a decision by the Secretary of the Interior to accept parcels of land within the State into trust for the benefit of an Indian tribe because the Due Process Clause protects individuals, not states); *DKT Mem'l Fund v. Agency for Int'l Dev.*, 887 F.2d 275, 283-85 (D.C. Cir. 1989) (finding under a zone-of-interests analysis that foreign non-governmental organizations did not have standing to challenge federal government policy as a violation of the First Amendment because the First Amendment affords no protection to aliens beyond the borders of the United States). Accordingly, the State plaintiffs' claims should be dismissed for the additional reason that the States lack prudential standing.

D. Plaintiffs' Claims Are Not Ripe

Even if the Court determines that one or more plaintiffs has standing, the Court nevertheless should dismiss this action because plaintiffs' claims are not ripe. "The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Nat'l Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 808 (2003) (quotation omitted). It "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over

administrative policies." *Id*. at 807. It also "protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id*. at 807-08.

A case ripe for judicial review cannot be "nebulous or contingent but must have taken on fixed and final shape so that a court can see what legal issues it is deciding, what effect its decision will have on the adversaries, and some useful purpose to be achieved in deciding them." *Public Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 244 (1952). In assessing ripeness, courts evaluate both "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967), *overruled on other grounds in Califano v. Sanders*, 430 U.S. 99, 105 (1977).

The Supreme Court discussed these two prongs of the ripeness analysis in *Abbott Laboratories*, the seminal case on pre-enforcement review of agency action. 387 U.S. 136. *Abbott Laboratories* involved a pre-enforcement challenge to Federal Food, Drug and Cosmetic Act regulations that required drug manufacturers to include a drug's established name every time the drug's proprietary name appeared on a label. *Id*. at 137-38. The regulations required the plaintiff drug manufacturers to change all their labels, advertisements, and promotional materials at considerable burden and expense. *Id*. at 152. Noncompliance would have triggered significant civil and criminal penalties. *Id*. at 153 & n.19.

The Court determined the regulations were fit for judicial review because they were "quite clearly definitive," *id*. at 151; the regulations "were made effective immediately upon publication," *id*. at 152, and "[t]here [was] no hint that th[e] regulation[s] [were] informal . . . or tentative." *Id*. at 151. Moreover, the Court noted that "the issue tendered [was] a purely legal one" and there was no indication that "further administrative proceedings [were] contemplated."

Id. at 149. The Court therefore was not concerned that judicial intervention would inappropriately interfere with further administrative action.

With respect to the hardship prong, the Court determined that delayed review would cause sufficient hardship to the plaintiffs. The impact of the regulations, the Court noted, was "sufficiently direct and immediate" because their promulgation put the drug manufacturers in a "dilemma" – "[e]ither they must comply with the every time requirement and incur the costs of changing over their promotional material and labeling" or they must "risk serious criminal and civil penalties for the unlawful distribution of misbranded drugs." *Id*. at 152-53 (quotation omitted). In other words, the challenged regulations "require[d] an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance." *Id*. at 153.

None of the indicia of ripeness discussed in *Abbott Laboratories* is present in this case. Defendants have initiated a rulemaking to amend the challenged regulations to accommodate the concerns expressed by plaintiffs and others that are similarly situated. Defendants, moreover, have made clear that the forthcoming amendments will be finalized well before the earliest date on which the challenged regulations could be enforced by defendants against certain non-profit organizations with religious objections to covering contraception – like the organization plaintiffs and the employers of the individual plaintiffs. 77 Fed. Reg. at 8728-29. Therefore, unlike in *Abbott Laboratories* – where the challenged regulations were definitive and no further administrative proceedings were contemplated – the regulations challenged here will be amended.

Furthermore, the forthcoming amendments are intended to address the very issue that plaintiffs raise in this case by establishing alternative means of providing contraceptive coverage

without cost-sharing while accommodating religious organizations' religious objections to covering contraceptive services. And plaintiffs will have several opportunities to participate in the rulemaking process and to provide comments and/or ideas regarding the proposed accommodations. There is, therefore, a significant chance that the amendments will alleviate altogether the need for judicial review, or at least narrow and refine the scope of any actual controversy to more manageable proportions. *See Texas v. United States*, 523 U.S. 296, 300 (1998) ("A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." (quotations omitted)). Once the forthcoming amendments are finalized, if plaintiffs' concerns are not laid to rest, plaintiffs "will have ample opportunity [] to bring [their] legal challenge at a time when harm is more imminent and more certain." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 734 (1998); *see also Texas Indep. Producers & Royalty Owners Ass'n v. EPA*, 413 F.3d 479, 483-84 (5th Cir. 2005) (dismissing challenge to rule as unripe where agency deferred effective date of rule and announced its intent to consider issues raised by plaintiff in new rulemaking during the deferral period); *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 50 (D.C. Cir. 1999) ("Prudence . . . restrains courts from hastily intervening into matters that may best be reviewed at another time or another setting, especially when the uncertain nature of an issue might affect a court's ability to decide intelligently." (quotation omitted)); *Lake Pilots Ass'n v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 160-162 (D.D.C. 2003) (holding challenge to rule was not ripe where agency undertook a new rulemaking to address issue raised by plaintiff in the lawsuit).

Additionally, although plaintiffs' complaint raises largely legal claims, those claims are leveled at regulations that, as related to the plaintiffs (and similarly-situated organizations and individuals), have not "taken on fixed and final shape." *Vorbeck v. Schnicker*, 660 F.2d 1260,

1266 (8th Cir. 1981). Once defendants complete the rulemaking outlined in the ANPRM, plaintiffs' challenge to the current regulations likely will be moot. *See The Toca Producers v. FERC*, 411 F.3d 262, 266 (D.C. Cir. 2005) (rejecting purely legal claim as unripe due to the possibility that it may not need to be resolved by the courts). And judicial review now of any future amendments to the regulations that result from the pending rulemaking would be too speculative to yield meaningful review. The ANPRM offers ideas and solicits input on potential means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations' religious liberty interests. 77 Fed. Reg. at 16503. It does not preordain what amendments to the preventive services coverage regulations defendants will ultimately promulgate; nor does it foreclose the possibility that defendants will adopt alternative proposals not set out in the ANPRM. Thus, review of any of the suggested proposals contained in the ANPRM would only entangle the Court "in abstract disagreements over administrative policies." *Abbott Labs.*, 387 U.S. at 148; *see also Minnesota Pub. Utils. Comm'n. v. FCC*, 483 F.3d 570, 582-83 (8th Cir. 2007) (concluding agency order that suggested agency would preempt certain state regulations in the future "if faced with the precise issue" was not ripe because "the order [did] not purport to actually do so and until that day comes it is only a mere prediction"); *Texas Indep. Producers*, 413 F.3d at 484; *Motor Vehicle Mfrs. Ass'n v. New York State Dep't of Envtl. Conservation*, 79 F.3d 1298, 1306 (2d Cir. 1996) (concluding claims were not ripe where "plaintiffs' arguments depend upon the effects of regulatory choices to be made by [state] in the future"); *Lake Pilots Ass'n*, 257 F. Supp. 2d at 162. Because judicial review at this time would inappropriately interfere with defendants' pending rulemaking and may result in the Court deciding issues that may never arise, this case is not fit for judicial review.

Withholding or delaying judicial review also would not result in any hardship for plaintiffs. Unlike the plaintiffs in *Abbott Laboratories*, plaintiffs here are not being compelled to make immediate and significant changes in their day-to-day operations under threat of serious civil and criminal penalties. As explained above, if the group health plans made available by the organization plaintiffs or by the employers of the individual plaintiffs are grandfathered – and there are no factual allegations in the complaint to indicate that they are not – then the plans are not required to cover contraceptive services. Moreover, even if the group health plans are not grandfathered, the organization plaintiffs and the employers of the individual plaintiffs can qualify for the temporary enforcement safe harbor, meaning defendants will not take any enforcement action against them for failure to cover contraceptive services until August 1, 2013, at the earliest. *See* Guidance at 3. And, by that time, defendants will have finalized amendments to the preventive services coverage regulations to further accommodate religious objections to providing contraceptive coverage. *See* 77 Fed. Reg. at 8728-29. Therefore, this is simply not a case where plaintiffs are forced to choose between foregoing lawful activity and risking substantial legal sanctions. *See Abbott Labs.*, 387 U.S. at 153; *see also Texas Indep. Producers*, 413 F.3d at 483 (finding no hardship where effective date of rule was one year away and agency had announced its intention to initiate a new rulemaking to address plaintiff's concerns). Indeed, "[w]ere [this Court] to entertain [the] anticipatory challenge[] pressed by [plaintiffs]" – parties "facing no imminent threat of adverse agency action, no hard choice between compliance certain to be disadvantageous and a high probability of strong sanctions" – the Court "would venture away from the domain of judicial review into a realm more accurately described as judicial preview," a realm into which courts should not tread. *Tennessee Gas Pipeline Co. v. FERC*, 736 F.2d 747, 751 (D.C. Cir. 1984) (internal citation omitted); *see also Missouri ex rel. Mo.*

Highway &Transp. Comm'n v. Cuffley, 112 F.3d 1332, 1337 (8th Cir. 1997) ("[Courts] may not render an opinion advising what the law would be upon a hypothetical state of facts." (quotation omitted)).

Because plaintiffs' challenge to the preventive services coverage regulations is not fit for judicial decision and plaintiffs would not suffer substantial hardship if judicial review were withheld or delayed, this case should be dismissed in its entirety as unripe.

II. THE COURT SHOULD DISMISS THE STATE PLAINTIFFS' CLAIMS FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

Even if the Court were to determine that it has jurisdiction over the claims asserted by the State plaintiffs on their own behalf, the Court nonetheless should dismiss those claims under Federal Rule of Civil Procedure 12(b)(6). The States claim that the preventive services coverage regulations violate the States' rights to free speech, free exercise of religion, and freedom of association under the First Amendment as well as the Religious Freedom Restoration Act. But neither the First Amendment nor RFRA provides any protection to states. Therefore, the State plaintiffs have failed to state a claim upon which relief may be granted.

The First Amendment "exists to protect individuals, not government." *Forbes v. Arkansas Educ. Television Comm'n*, 93 F.3d 497, 505 (8th Cir. 1996), *rev'd on other grounds*, 523 U.S. 666 (1998), *and subsequently vacated*, 145 F.3d 1017 (8th Cir. 1998); *see also Parker*, 478 F.3d at 383 ("Every other provision of the Bill of Rights, excepting the Tenth, which speaks explicitly about the allocation of governmental power, protects rights enjoyed by citizens in their individual capacity."); *Warner Cable Commc'ns, Inc. v. City of Niceville*, 911 F.2d 634, 638 (11th Cir. 1990) (observing that the Free Speech Clause does not protect the government). *Cf. Lyons v. United States*, 99 Fed. Cl. 552, 560 (2011) ("[F]undamental rights protected by the federal Bill of Rights . . . apply only to individual persons, not to the federal government.");

EEOC v. Mitsubishi Motor Mfg. of Am., Inc., 102 F.3d 869, 871 (7th Cir. 1996) ("The Executive Branch of the federal government does not have rights under the [F]irst [A]mendment."). The same is true of RFRA. RFRA prohibits the "government [from] substantially burden[ing] a *person's* exercise of religion" unless the government demonstrates that it is the least restrictive means of furthering a compelling governmental interest. 42 U.S.C. § 2000bb-1 (emphasis added). Congress enacted RFRA with the express aim of restoring what, in Congress's view, the Free Exercise Clause of the Constitution guaranteed prior to the Supreme Court's decision in *Employment Division v. Smith*, 494 U.S. 872 (1990). 42 U.S.C. § 2000bb. Accordingly, the "persons" to whom RFRA applies should be interpreted to be consistent with the reach of the First Amendment. *See Rasul*, 563 F.3d at 532-33. Because the First Amendment does not protect states, neither does RFRA.[15]

Indeed, it would be absurd to suggest that states have rights under the Free Exercise Clause and RFRA. Those provisions prohibit the government from imposing a substantial burden on a person's exercise of religion (whether via a non-neutral, non-generally-applicable law or otherwise) absent a compelling governmental interest and narrow tailoring. 42 U.S.C. § 2000bb-1; *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546 (1993). States, however, are prohibited from advancing, endorsing, or exercising any religion by another

[15] The term "person" as used in RFRA does not include states for the additional reason that Congress included states within the definition of "government" under RFRA. RFRA prohibits certain actions by "government" – a term that, prior to the Supreme Court's decision in *City of Boerne v. Flores*, included states. 521 U.S. 507, 516 (1997) (citing prior version of 42 U.S.C. § 2000bb-2(1) that defined "government" to include any "State"). It would be inconsistent with principles of statutory construction to interpret "person" as used in RFRA to include states when Congress used a different term in the same provision, i.e., "government," to refer to states. *See Furnes v. Reeves*, 362 F.3d 702, 713 (11th Cir. 2004) ("It is a fundamental rule of statutory interpretation that, within an act, the same words have the same meanings and different words have different meanings."); *Lindsey v. Tacoma-Pierce Cnty. Health Dep't*, 195 F.3d 1065, 1074 (9th Cir. 1999) (recognizing "basic principle of statutory construction that different words in the same statute must be given different meanings").

constitutional provision – the Establishment Clause. *See Engel v. Vitale*, 370 U.S. 421, 431 (1962) ("When the power, prestige and financial support of government is placed behind a particular religious belief, the indirect coercive pressure upon religious minorities to conform to the prevailing officially approved religion is plain."); *Cantwell v. State of Connecticut*, 310 U.S. 296, 303 (1940). Thus, the State plaintiffs cannot show that their exercise of religion has been substantially burdened – as required by the First Amendment and RFRA – without purporting to endorse a religion – which would violate the Establishment Clause. For these reasons, if the Court determines it has jurisdiction over the claims that the State plaintiffs assert on their own behalf, the Court should dismiss those claims under Rule 12(b)(6).

CONCLUSION

For all the foregoing reasons, this Court should grant defendants' motion to dismiss.

Respectfully submitted this 30th day of April, 2012,

STUART F. DELERY
Acting Assistant Attorney General

IAN HEATH GERSHENGORN
Deputy Assistant Attorney General

DEBORAH K.R. GILG,
United States Attorney

JENNIFER RICKETTS
Director

SHEILA M. LIEBER
Deputy Director

s/ Michelle R. Bennett
MICHELLE R. BENNETT (CO Bar No. 37050)
ERIC R. WOMACK
JAMES D. NELSON
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue N.W. Room 7310
Washington, D.C. 20530
Tel: (202) 305-8902
Fax: (202) 616-8470
Email: michelle.bennett@usdoj.gov

Attorneys for Defendants.

CERTIFICATE OF SERVICE

I certify that on this 30th day of April 2012, I caused a copy of the foregoing Defendants' Memorandum of Law in Support of their Motion to Dismiss to be filed electronically and that the document is available for viewing and downloading from the ECF system.

s/ Michelle R. Bennett
Michelle R. Bennett